

What is claimed is:

1. A spinal fusion implant for fusing together two adjacent vertebra comprising:

a first member having first and second opposing sides and a first bore defining a central longitudinal first axis, the first bore being in communication with at least the first side;

a second member having third and fourth opposing sides and a second bore in communication with at least the third side, the second bore defining a second central longitudinal axis, the first and second axes forming a first pair; and

an elongated first pin located in the first and second bores for securing the first member to the second member at the interface formed by the facing first and third respective sides, the pin having a first section defining a third central longitudinal axis and a second section defining a fourth central longitudinal axis, the third and fourth axes forming a second pair;

one axis of at least one of the first and second pair of axes being offset relative to the other axis of the at least one pair of axes so as to place the pin in relative compression and tension in the first and second bores for providing a compressive load on the surface of the first and second bores to frictionally secure the members together.

20

2. The implant of claim 1 wherein the first and second members and pin each comprise cortical bone, the pin and bores having approximately the same transverse dimensions.

5 3. The implant of claim 1 wherein the first and second members are bonded to at least one of 1) to each other or 2) to at least one of the pins.

10 4. The implant of claim 2 wherein the members and pins are each formed from a bone having a given fiber direction such that the bone resists shearing in a direction transverse to the fiber direction to a significantly greater extent than in a direction parallel to the given direction, the longitudinal axes of the pin sections all being substantially along the fiber direction.

15 5. The implant of claim 2 wherein the member sides each define a plane and the members and pins are each formed from a bone having a given fiber direction such that the bone resists a tensile force and a shearing force in a direction transverse to the fiber direction to a significantly greater extent than in a direction parallel to the given direction, the bone members each having a fiber direction approximately parallel to the planes.

20

6. The implant of claim 1 wherein the members each have a length and a width defining a plane and a thickness normal to the plane, the members being cortical bone, the bone of the members having fibers extending in a given direction approximately parallel to the plane.

5

7. The implant of claim 1 wherein the first and second members define a planar interface, further including an interengaging arrangement coupled to the first and second members adjacent to said interface for precluding translation displacement of the members transverse to said first and second axes in response to said compression load on said surface of said bores .

10

8. The implant of claim 7 wherein the interengaging arrangement comprises a further bore in each said members in communication with each other and an interconnecting pin in each said further bore, the interconnecting pin having a longitudinal axis extending through and transverse to said interface.

15

9. The implant of claim 7 wherein the first member has a planar interface surface at said first side, the second member having a planar interface surface at the third side for abutting said first member planar surface in a plane, the first member defining an edge, the second member having a leg extending therefrom, the leg

20

for abutment with the edge to form said interengaging arrangement to preclude relative translation of the first and second members in at least one direction in said plane, said compression and tension creating compression forces in said members in said at least one direction.

5

10. The implant of claim 9 wherein the second member is L-shaped with the leg forming a recess with the second member planar interface surface, the first member being located in said recess.

10

11. The implant of claim 10 wherein each member is L-shaped with the leg of each member forming a recess with its planar interface surface, each member having a portion adjacent to its leg in the recess of the other member

15

12. The implant of claim 1 wherein the axes of the first pair of axes are offset relative to each other and the axes of the second pair of axes are coaxial.

13. The implant of claim 1 wherein the axes of the first pair of axes are coaxial and the axes of the second pair of axes are offset relative to each other.

20

14. The implant of claim 1 wherein the offset is formed by the at least one axis being parallel to and spaced from said other axis.

5 15. The implant of claim 1 wherein the offset is formed by the at least one axis being non-parallel to said other axis.

16. The implant of claim 15 wherein the one and other axes intersect.

10 17. The implant of claim 1 wherein the first and second sections are curved forming said second pair of axes as a single continuous curved axis.

15 18. The implant of claim 1 wherein the sections are selected from one or more of the group consisting of transverse square cross section, transverse circular cross section, transverse elliptical cross section, a polygon transverse cross section, a triangular cross section, a multiple sided elongated figure, an elongated element with one or more elongated ribs extending radially therefrom, an elongated element with one or more projections extending radially therefrom and any combination thereof.

20

19. The implant of claim 18 wherein the pin has a longitudinal axis and is cortical bone having a fiber direction in the general direction of the longitudinal axis.

20. The implant of claim 1 wherein the first member includes a third bore and the second member includes a fourth bore in communication with the third bore, and a further pin in the third and fourth bores.

21. The implant of claim 20 wherein the first and second bores form a first elongated bore and the third and fourth bores form a second elongated bore, said first and second elongated bores lying in spaced parallel planes, the projection of the first and second elongated bores in a direction normal to said planes forming an X shaped image of said first and second elongated bores in a plane parallel to said parallel planes.

22. The implant of claim 20 wherein the elongated pin and the further pin are different in outer peripheral shape.

23. The implant of claim 20 wherein the further pin is circular cylindrical.

24. The implant of claim 1 wherein the bores are inclined non-perpendicular to the interface.

25. The implant of claim 1 including two sets of said first and second bores and a second pin, the first pin engaged with the first set of bores and the second pin engaged with the second set of bores.

26. The implant of claim 25 wherein only the first set of bores have offset axes relative to each other and the first and second sections of each of the first and second pins have coaxial axes.

27. The implant of claim 25 wherein only the first pin has offset first and second sections, the second pin and first and second bores of both sets of bores comprising coaxial through bores.

28. The implant of claim 25 wherein the implant is elongated defining a longitudinal axis, the two sets of bores being spaced from each other along the longitudinal axis of the implant.

29. The implant of claim 25 wherein the implant is elongated defining a longitudinal axis, the two sets of bores being spaced apart in a direction transverse to the implant longitudinal axis.

5 30. The implant of claim 25 wherein each set of bores are inclined at an angle not perpendicular to the plane of the interface of the members, the angle of one set of bores being oriented opposite to the orientation of the other set of bores.

10 31. The implant of claim 30 wherein the first and second axes of each set of bores are offset.

32. The implant of claim 30 wherein the third and fourth axes of the respective first and second sections of each pin are offset relative to each other.

15 33. The implant of claim 1 wherein the members each comprise sheet material, the sheet material having opposing surfaces defining said sides, the members forming a wedge having proximal and distal ends, the proximal end forming an anterior end and the distal end forming a posterior end, the implant having a longitudinal axis along the interface of said members extending through said
20 proximal and distal ends parallel to the interface of said members.

34. The implant of claim 1 wherein the members each comprise sheet material, the sheet material having opposing surfaces defining said sides, the members forming a wedge having proximal and distal ends, the proximal end forming an anterior end and the distal end forming a posterior end, the implant having a longitudinal axis normal to the interface of said members and extending through said proximal and distal ends normal to the interface of said members, the elongated first pin extending along said longitudinal axis.

35. A pin for interconnecting a plurality of bone elements in an implant comprising:

an elongated member having a longitudinal length dimension and comprising cortical bone having a fiber direction, the fiber direction extending in the length dimension, the member having first and second sections which are offset relative to each other in the radial direction transverse to the longitudinal length direction.

36. The pin of claim 35 wherein each section comprises a circular cylindrical segment defining a central longitudinal axis, said axes being parallel and spaced from each other.

37. The pin of claim 35 wherein the pin sections form a continuous curve.

38. The pin of claim 36 wherein the curve approximates a segment of a circle.

5 39. The pin of claim 36 wherein the curve approximates a segment of an ellipse.

40. The pin of claim 35 wherein the axes of said sections are linear and intersect at a non-perpendicular angle.

10 41. The pin of claim 35 wherein the sections each have a curved outer peripheral surface forming a curved transverse cross section.

42. The pin of claim 35 wherein the sections are different in shape or length.

15 43. The pin of claim 35 wherein the sections are substantially the same and interconnected.

44. The pin of claim 35 wherein the sections are mirror images of each other.

20

45. The pin of claim 35 wherein the elongated member comprises a shank portion having said length dimension and a rib portion extending radially from the shank portion.

5 46. The pin of claim 35 wherein the elongated member has an annular outer surface defining a non-circular geometrical shape.

47. The pin of claim 46 wherein the pin in transverse section is a polygon.

10 48. The pin of claim 35 wherein the elongated member has a textured outer surface.

49. The pin of claim 48 wherein the outer surface is knurled.

15 50. The pin of claim 48 wherein the outer surface is irregularly roughened.

51. The pin of claim 48 wherein the outer surface comprises annular grooves.

52. The pin of claim 51 wherein the grooves form at least one thread.

20

53. The pin of claim 46 wherein the elongated member has opposing ends and an outer convex curved surface in longitudinal sectional profile, the outer surface having a first diameter intermediate the ends greater than a second diameter spaced from the first diameter and adjacent to the ends.

5

54. The pin of claim 46 wherein the member has opposing ends and an outer concave surface in longitudinal sectional profile.

55. The pin of claim 35 wherein the pin is surface demineralized.

10

56. The pin of claim 35 wherein the pin has a further section, said further section being fully demineralized.

57. The pin of claim 35 wherein the pin is fully demineralized.

15

58. A spinal implant comprising:

first and second cortical bone members each having a pin receiving bore at an interface therebetween;

means for resisting translation of the members relative to each other in any

20 given direction; and

a cortical bone pin in the bores for connecting the bone members;
one of the pin and mating bores being offset relative to each other to
create a compressive and/or tensile force in the pin to create a static friction load
to lock the pin to the bone members in the given direction.

5

59. The implant of claim 58 wherein the bores are surfaced demineralized.

60. A cortical bone implant comprising:

10

a first cortical bone member having a first bore;
a second cortical bone member having a second bore; and
a connecting pin attached to each member in said bores;
means for placing the pin in both compression and tension to frictionally
hold the pin to the members and the members together.

15

61. The implant of claim 60 wherein at least one of the pin and the first and
second bores is surface demineralized.

62. A cortical bone implant comprising:

20

a first cortical bone member;
a second cortical bone member abutting the first member, each member

having a pin receiving bore; and

a pin, the pin being in each member bore for attaching the members to each other, the pin and bores being arranged to place the pin in both compression and tension.

5

63. The implant of claim 62 including a pair of said pins and a pair of mating bores in the members, at least one of the pins and mating bores being arranged to place the pin in said compression and tension.

10

64. The implant of claim 62 including a pair of said pins and a pair of mating bores in the members, both pins and mating bores being arranged to place the pins in said compression and tension.

15

65. The implant of claim 64 wherein the implant extends in a longitudinal direction, the pins being axially spaced in the longitudinal direction.

66. The implant of claim 64 wherein the implant extends in a longitudinal direction, the pins being spaced transversely relative to the longitudinal direction.

20

67. The implant of claim 66 wherein each pin and its mating bores include corresponding offset means for creating said tension and compression, the offset means corresponding to one pin being oriented in an opposite direction to the offset means corresponding to the other pin.

5

68. The implant of claim 64 wherein each said pin of the pair of pins and mating bores includes means arranged to cause one pin to exhibit compression and tension in opposing mirror image directions to the other pin.

10

69. The implant of claim 64 wherein the bores of each mating pair each define an axis and the bores of each pair are offset axially relative to each other.

15

70. The implant of claim 64 wherein the pins have first and second axially extending end sections, the end section of at least one of said pins being offset axially from the other end section of that at least one pin.

71. The implant of claim 62 including three cortical bone members, each member having a bore for receiving the pin, the pin being in said compression and tension in at least two of said bone members.

20

Amicus
AI
73. An implant comprising:

a first planar member having two opposing broad surfaces having a periphery defining a first plurality of edges;

Sub AI
a second L-shaped member having a first base member defined by a second plurality of edges and a first leg extending from the base member at one base member edge forming a first recess, the first member being disposed in the first recess with an edge of the first member abutting the first leg, the edges of the first base member and the edges of the first member being coextensive; and means for securing the first member to the second member.

13
74. The implant of claim 73 wherein the abutment of the first member with the second member leg preclude translation of the first member in a direction toward the leg, the means for securing including a pin in the first and second members under tension and compression to provide a relative compressive load between the first and second members in a direction to force the first member toward said leg.

74
75. The implant of claim 73 wherein the first member is L-shaped including a second leg and a second base member which forms a second recess, the first and second base members overlying each other with the first leg overlying an

edge of the second base member and the second leg overlying an edge of the first base member.

75
76. An implant comprising:

5 a first L-shaped member having a first base portion and a first leg portion;
a second L-shaped member having a second base portion and second leg portion;

a third planar member disposed between the first and second base portions and between the first and second leg portions;

10 and means for securing the members together.

76
77. The implant of claim 76 wherein the means for securing comprises a pin in interference fit with a corresponding bore in at least the first and second members.

77
78. The implant of claim 77 wherein the bores of the first and second members and the pin are arranged to place the pin in both compression and tension to provide a compressive load on the first and second members.

78
79. The implant of claim 77 wherein the first and second members are cortical bone.

20

80. A spinal implant comprising:

a stacked plurality of planar cortical bone sheets each with a bore, the implant having a length dimension in a given direction, the sheets each having an abutting interface surface extending in the length direction with the corresponding bore at said interface; and

means including a pin extending transversely the length direction in said bores for securing the sheets together, the bores and pin being arranged so that the pin exhibits compressive and tensile forces for applying a compressive load on at least two of said sheets to hold the sheets together.

81. A spinal implant comprising:

a stacked plurality of planar cortical bone sheets, the implant having a length dimension in a given direction, the sheets each having an interface surface abutting an adjacent sheet extending transversely the length direction and a bore at the interface surface; and

a cortical bone pin extending in the length direction in said bores for securing the sheets together.

82. The implant of claim 81 wherein the bores and pin are arranged so that the pin exhibits compressive and tensile forces for applying a compressive load on at

least two of the sheets.

82
83. A spinal implant comprising:

5 a member of formed of cortical bone, the member having an anterior end defined by an anterior end surface and a posterior end defined by a posterior end surface, the implant having first and second side surfaces terminating at said end surfaces, the side surfaces comprising mirror image continuous curved surfaces.

83
84. The implant of claim 83 wherein the curved surfaces are convex.

10 84
85. The implant of claim 83 wherein the member has first and second opposing surfaces that are inclined relative to each other terminating at said end surfaces so that the anterior end is greater in height between the opposing surfaces than the posterior end,

15 85
86. The implant of claim 84 wherein the curved surfaces are each defined by at least one radius.

20

100523 120501

87. A cortical bone implant member comprising:

a cortical bone plank defined by opposing sides each having a surface, the plank being surrounded by a peripheral edge, the plank having a fiber direction generally parallel to the opposing side surfaces, the plank have a length dimension and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the plank having at least one through bore in communication with said sides.

88. A bone implant comprising:

first and second cortical bone planks each defined by opposing sides each side having a surface and surrounded by a peripheral edge, the planks having a fiber direction generally parallel to the opposing side surfaces, each plank having a length dimension defining a longitudinal direction and a transverse width dimension smaller than the length dimension, the fiber direction being generally parallel to the width dimension, the planks each having at least one through bore in communication with said side surfaces; and

a cortical bone pin in interference fit with each said bores wherein the pin applies a compressive load on the corresponding planks in opposing longitudinal directions.

1005238-12504

88
89. A method of forming a bone implant comprising:

assembling two cortical bone planks in parallel abutting relation;

boring at least one first bore in one of the bone planks in a first direction;

and

5 boring at least one second bore in the other of the bone planks in a second direction generally opposite the first direction wherein the first and second bores are offset relative to each an amount such that a straight bone pin inserted in the bores is placed in compression and tension.

89
10 90. The method of claim 89 wherein the bores have parallel axes.

90
91, The method of claim 89 wherein the offset of the axes is in the range of about 0.1-10 mm.

91
15 92. The method of claim 91 wherein the offset comprises forming the first bore with its axis at an angle to the axis of the second bore.

92
93. The method of claim 91 wherein the first and second bores are at a first angle relative to the planks, further including boring third bore in the first plank and a
20 boring a fourth bore in the second plank at a second angle different than the first

angle.

93
94. The method of claim 93 wherein the planks have an interface defining a plane, the method including boring the first and second bores at a first angle that is non-perpendicular with respect to the plane of the planks.

94
95. The method of claim 94 wherein the third and fourth bores are bored at a second angle that is non-perpendicular with respect to the plane of the planks but in mirror image relation to the first and second bores.

95
96. The method of claim 94 wherein the third and fourth bores are bored at a second angle normal to the plane of the planks.

96
97. A method of forming an implant comprising:
forming first and second cortical bone planks;
forming a bore in each said planks; and
inserting a bone pin in the bores so as to cause the pin to exhibit both compressive and tensile loads which compressively secure the planks to the pin.

97
98. The method of claim 97 including forming the pin from cortical bone exhibiting a fiber direction, the pin having a length dimension, the fiber extending in the length direction.

98
5 99. The method of claim 97 including surface demineralizing the bores.

99
100. The method of claim 97 including demineralizing at least the surface of said pin.

100
10 101. The method of claim 97 including surface demineralize said bores and said pin.

101
102. The method of claim 97 including fully demineralizing at least a portion of the pin and surface demineralizing the implant and said bores.

102
15 103. A method of forming a bone implant comprising:

clamping a bone between first and second clamp members such that an end portion of the bone overhangs an end of the clamp members; and

removing a portion of the overhanging end portion of the bone to form an
20 implant plank.

104. A method of forming an implant comprising:

forming a plurality of implant members each defining a plane;

abutting the members; and

attaching a pin to the abutting members transverse to the plane and

5 creating opposing compressive forces against the members by creating
compressive and tensile bending loads in the pin to resist forces which otherwise
tend to separate the members.

105. The method of claim 104 including forming the implant members of cortical
10 bone.

106. The method of claim 104 including forming the pin of cortical bone.

107. The method of claim 104 wherein the step of attaching includes bending the
15 pin during the insertion of the pin into bores in the members.

108. The method of claim 104 wherein the step of forming the implant members
includes the step of forming the implant members with first and second offset
bores and the step of attaching includes forming a straight cylindrical pin and
20 forcing the pin into the offset bores to bend the pin.

108
109. The method of claim 104 wherein the step of forming the implant members includes forming first and second aligned bores of substantially the same transverse dimension in each member and the step of attaching the pin includes
5 forming the pin with offset sections and then inserting the offset sections into said bores to bend the pin.

109
110. The method of claim 104 wherein the implant has load bearing surfaces, the members comprising fibrous bone having a given fiber direction, further including
10 forming the implant with the bone fiber direction normal to the load bearing surfaces.

110
111. A method of forming an implant comprising:
forming first and second cortical bone members with a bore in each
15 member;
contracting a cortical bone pin by dehydrating the pin;
inserting the dehydrated pin in the bore of each member; and then
expanding the inserted pin to create an interference fit between the pin
and bone members in the bores.

20

111
112. The method of claim 111 wherein the expanding step comprises immersing the inserted pin and attached bone members in a fluid solution.

112
113. The method of claim 111 wherein the dehydrating contracting step includes placing the pin in a vacuum.

113
114. The method of claim 111 wherein the expanding step includes hydrating the pin.

114
10 115. A spinal implant comprising:
first and second cortical bone planks each having fibers oriented in a direction parallel to a vertebral load thereon and normal to an insertion direction into the disc space between adjacent vertebra;
each plank having a demineralized load bearing surface for abutting an
15 adjacent vertebra; and
means for securing the planks to each other with the demineralized surfaces coextensive.

115
115. The implant of claim 114 wherein the means for securing comprises a
20 cortical bone pin in a bore of each plank, the pin having bone fibers extending in

the length direction of the pin, a surface of the pin being demineralized.

116. The implant of claim 114 wherein the means for securing comprises a cortical bone pin in a bore of each plank, the pin having bone fibers extending in
5 the length direction of the pin and wherein the surfaces of the bores receiving the pin are demineralized.

117. A cortical bone implant comprising:

first and second mirror image blocks of substantially the same shape and
10 dimensions formed of cortical bone, each block having opposing ends, a projection extending from one end and a slot formed in the other end, the slot of one block receiving the projection of the other block to form an assembled six sided implant.

15 118. An implant comprising:

a body comprising first and second cortical bone members having an oval outer peripheral surface and two opposing planar surfaces at opposite edges of the oval surface; and

mechanical interconnection means for connecting the first and second
20 members.

119. The implant of claim 118 wherein the connection means comprises a dovetail joint.

120. The implant of claim 118 wherein the connection means comprises a pin
5 inserted into corresponding bores of the members and in friction interference fit with the members.

121. The implant of claim 118 wherein the interconnection means comprises interengaging slots.

10 122. A bone implant comprising:

first and second cortical bone members;

each member comprising a segment of a ring of cortical bone and including a plurality of slots, the slots being arranged so that the slots of the first and second
15 members interengage to mechanically secure the members together into a single structure.

123. A process for forming a bone implant comprising:

forming a plurality of planks of cortical bone, the planks having a broad
20 surface terminating at edges, the surface being defined by a length and a width,

the planks each having a thickness;

forming the broad surface of each of at least two of said planks for mating in abutting relation;

surface demineralizing all surfaces of the at least two planks;

5 clamping together the two at least planks with said mating broad surfaces abutting;

washing the clamped at least two planks;

forming at least one bore in the at least two clamped planks transversely the broad surfaces for receiving a locking pin therein;

10 forming a locking pin and inserting the locking pin in said at least one bore in each of the at least two clamped planks;

forming a plurality of ridges on first and second opposing sides of said clamped planks;

surface demineralizing the formed ridges;

15 freezing and/or drying under clamping pressure the resulting demineralized implant; and then

unclamping the implant.

124. The process of claim 123 including forming surface features in said broad
20 mating surfaces.

125. The process of claim 124 wherein said surface features include interlocking elements for locking the at least two planks from relative displacement in the plane of said mating surfaces in at least one direction.

5 126. The process of claim 123 including providing compression and tensile loads on said inserted pin to provide compression loads on the mating at least two implants in at least one direction.

127. A spinal implant comprising:

10 first and second planks of cortical bone each plank having opposing broad surfaces, the bone having fibers running generally in a direction parallel to the broad surfaces of each plank;

a broad surface of each plank being surface demineralized and abutting, the demineralized surfaces having an acid applied thereto to form crystals on the deminerlized surface of each plank; and

15 forcing the abutting wet surfaces together to join the planks by interlocking the formed crystals of each bone;

the planks each having at least one bore that is surface deminerallized, the bore having a longitudinal axis that is normal to the fiber direction; and

20 a cortical bone pin in the plank bores for securing the planks together.

128. The implant of claim 127 wherein the bone pin is surface demineralized.

129. A process of making a spinal implant comprising:

forming first and second hydrated cortical bone planks with aligned bores;

5 surface demineralizing a bone pin and then dehydrating the pin;

inserting the dehydrated pin into the aligned bores; and then

swelling the demineralized pin surface to provide a friction fit between the
pin and bores.

10 130. The process of claim 129 including surface demineralizing the bores.

131. The process of claim 129 including forming the bores with the plank bone
fibers normal to the longitudinal axes of the bores.

15 132. A method of forming a bone pin comprising:

passing a bone through a set of a plurality of cutting dies of progressively
smaller bore sizes to form the pin of a given peripheral dimension and shape
from a bone of a larger peripheral dimension.

20

133. The method of claim 132 wherein the dies progressively differ from each other in transverse shape.

134. The method of claim 132 including surface demineralizing at least a portion
5 of the pin after said passing.

135. The method of claim 132 including demineralizing at least a section of the pin to make the demineralized section flexible.

10 136. The method of claim 132 including forming surface features on the pin outer peripheral surface during said passing.

137. The method of claim 136 wherein the surface features are selected from any one or more of the group consisting of flutes, ribs and channels.

15 138. The method of claim 132 including forming a surface roughness on the peripheral outer surface of the formed pin.